

Office of Research and Development

Human Health Risk Assessment



Products and Outputs in FY17

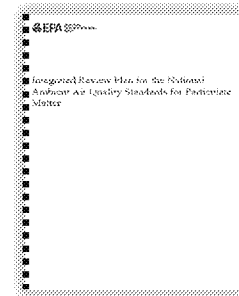
December 6, 2017

ISA CONTRIBUTION TO THE INTEGRATED REVIEW PLAN FOR PARTICULATE MATTER

CONTACT: STEVE DUTTON / [JASON SACKS](#) (NCEA-RTP)

Description: Develop the Integrated Science Assessment (ISA) chapter in the Draft Integrated Review Plan (IRP) to support the primary and secondary NAAQS review for particulate matter (PM).

Purpose: ORD/NCEA and OAR/OAQPS work collaboratively to develop the IRP that presents the schedule for the entire NAAQS review, the process for conducting the review, and the key policy-relevant science issues that will guide the review. NCEA is responsible for developing the ISA chapter within the IRP.



ISA CONTRIBUTION TO THE INTEGRATED REVIEW PLAN FOR PARTICULATE MATTER

CONTACT: STEVE DUTTON / JASON SACKS (NCEA-RTP)

- Draft PM IRP was released in April 2016, and subsequently reviewed by CASAC in August 2016 in a public teleconference
- Final PM IRP was published in December 2016
- ISA chapter detailed the policy-relevant questions that the ISA will address, specifically focusing on uncertainties and limitations in the evidence outlined in the 2009 PM ISA
- Additionally, the chapter detailed the scope of the health effects evaluation, and specifically the assessment of cancer
 - For health effects:
 - Composite metric of PM
 - Some method to assess the PM effect due to whole mixture exposure (e.g., diesel)
 - For cancer:
 - Differentiate EPA's assessment of PM and cancer from IARC's

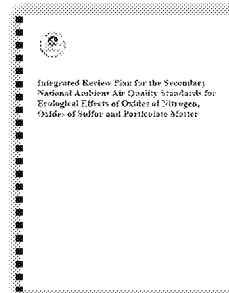
Key Product delivered to OAR/OAQPS on schedule in FY17 Q1. The complete Final IRP including contributions from both OAQPS and NCEA was publically posted in Q1 with notice of availability published in the FRN on Dec 6, 2016.

ISA CONTRIBUTION TO THE INTEGRATED REVIEW PLAN FOR OXIDES OF NITROGEN, OXIDES OF SULFUR, AND PARTICULATE MATTER

CONTACT: STEVE DUTTON / [TARA GREAYER](#) (NCEA-RTP)

Description: Develop the Integrated Science Assessment (ISA) chapter in the Final Integrated Review Plan (IRP) to support the secondary NAAQS review for oxides of nitrogen (NO_x), oxides of sulfur (SO_x), and particulate matter (PM).

Purpose: ORD/NCEA and OAR/OAQPS work collaboratively to develop the IRP that presents the schedule for the entire NAAQS review, the process for conducting the review, and the key policy-relevant science issues that will guide the review. NCEA is responsible for developing the ISA chapter within the IRP.



ISA CONTRIBUTION TO THE INTEGRATED REVIEW PLAN FOR OXIDES OF NITROGEN, OXIDES OF SULFUR, AND PARTICULATE MATTER

CONTACT: STEVE DUTTON / [TARA GREAYER](#) (NCEA-RTP)

- Draft NO_xSO_xPM IRP was released in October 2015, and subsequently reviewed by CASAC in December 2015 in a public teleconference
- Final NO_xSO_xPM IRP was published in January 2017
- The ISA chapter detailed the policy-relevant questions that the ISA will address, specifically focusing on evaluating new evidence published since 2008 on ecological effects of NO_x, SO_x and PM
- Additionally, the chapter detailed the scope of the ecological effects evaluation and key effects of NO_x, SO_x, and PM:
 - Biological and geochemical effects of terrestrial and aquatic (freshwater and marine) acidification
 - Biological and geochemical effects of terrestrial, wetland and aquatic (freshwater and marine) eutrophication
 - Ecosystem Services altered by NO_x, SO_x, and PM

Key Product delivered to OAR/OAQPS on schedule in FY17 Q1. The complete Final IRP including contributions from both OAQPS and NCEA was publically posted in Q2 and included in the public docket for this review. However, as of FY17 Q4, OAQPS has yet to receive permission to publish availability of this document in the FRN.

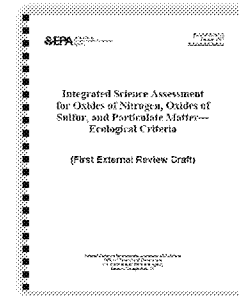
Note: this review now includes PM; OAQPS has yet to receive permission to publish availability of this document in the FRN.

FIRST DRAFT INTEGRATED SCIENCE ASSESSMENT FOR OXIDES OF NITROGEN, OXIDES OF SULFUR, AND PARTICULATE MATTER - ECOLOGICAL CRITERIA

CONTACT: STEVE DUTTON / [TARA GREAYER](#) (NCEA-RTP)

Description: Release the First Draft Integrated Science Assessment (ISA) for Oxides of Nitrogen, Oxides of Sulfur, and Particulate Matter - Ecological Criteria (NO_xSO_xPM-Eco) to support the secondary NAAQS for NO₂, SO₂, and PM.

Purpose: The ISA is a comprehensive review, synthesis, and evaluation of the most policy-relevant science and serves as the scientific foundation for the NAAQS review. It includes key science judgments that are important to inform the development of the risk and exposure assessments, as well as other aspects of the NAAQS review.



FIRST DRAFT INTEGRATED SCIENCE ASSESSMENT FOR OXIDES OF NITROGEN, OXIDES OF SULFUR, AND PARTICULATE MATTER - ECOLOGICAL CRITERIA

CONTACT: STEVE DUTTON / [TARA GREAYER](#) (NCEA-RTP)

- The scope of this review now includes PM, the first time all three of these criteria pollutants are reviewed together
- 1st Draft ISA released in March 2017
 - Key Product publically posted on schedule in Q2 with notice of availability and public comment period published in the FRN on Mar 30, 2017
- CASAC reviewed the 1st Draft ISA at a public meeting in May 2017; their final letter to communicate their comments was conveyed in September 2017
- There are 19 determinations in the first draft NO_xSO_xPM-Eco ISA
 - 14 determinations that remain causal from the 2008 NO_x-SO_x ISA
 - In each case there is new science adding weight of evidence and/or broader application
 - 5 determinations are new:
 - 3 causal
 - 1 likely causal
 - 1 suggestive of a causal relationship

Key Product publically posted on schedule in Q2 with notice of availability and public comment period published in the FRN on Mar 30, 2017.

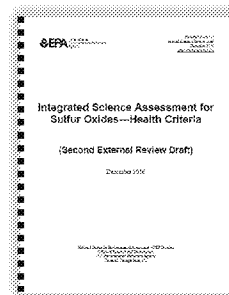
Note: this review now includes PM.

SECOND DRAFT INTEGRATED SCIENCE ASSESSMENT FOR SULFUR OXIDES - HEALTH CRITERIA

CONTACT: STEVE DUTTON / [TOM LONG](#) (NCEA-RTP)

Description: Release the Second Draft Integrated Science Assessment (ISA) for Sulfur Oxides - Health Criteria (SO_x-Health) to support the primary NAAQS for SO_x.

Purpose: The ISA is a comprehensive review, synthesis, and evaluation of the most policy-relevant science and serves as the scientific foundation for the NAAQS review. It includes key science judgments that are important to inform the development of the risk, exposure, and policy assessments, as well as other aspects of the NAAQS review.



SECOND DRAFT INTEGRATED SCIENCE ASSESSMENT FOR SULFUR OXIDES - HEALTH CRITERIA

CONTACT: STEVE DUTTON / [TOM LONG](#) (NCEA-RTP)

- 2nd Draft SO_x ISA revised in response to comments from CASAC and the public on the 1st Draft ISA released in November 2015
- CASAC reviewed the 2nd Draft ISA at a public meeting in March 2017; their review is now complete
- Final ISA to be released by Dec 14, 2017 under a court-ordered deadline
- Main conclusion of the ISA unchanged from the 2008 SO_x ISA:
 - There is a causal relationship between short-term exposure and respiratory effects based on evidence from controlled human exposure studies of exercising individuals with asthma
- For long-term exposure and respiratory effects, the evidence is suggestive of a causal relationship (change from 2008 SO_x ISA)
- The evidence is also suggestive of a causal relationship between short-term exposure and mortality

Key Product publicly posted ahead of schedule in Q1 with notice of availability and public comment period published in the FRN on Dec 9, 2016.

DEVELOPMENT OF PROVISIONAL PEER-REVIEWED TOXICITY VALUE (PPRTV) ASSESSMENTS

CONTACT: TERESA SHANNON (NCEA)

Description: PPRTVs currently represent a tier of human health toxicity values for the EPA Superfund and Resource Conservation and Recovery Act (RCRA) hazardous waste programs. Priorities for PPRTV development are based on the needs of the Office of Land and Emergency Management (OLEM) and evaluated annually.

Purpose: PPRTV assessments provide toxicity values derived for use in EPA's Superfund program to determine cleanup goals during remedial investigations when a value is not available in the IRIS database.



DEVELOPMENT OF PROVISIONAL PEER-REVIEWED TOXICITY VALUE (PPRTV) ASSESSMENTS

CONTACT: TERESA SHANNON (NCEA)

Research Approach: PPRTVs are derived using accepted, credible, and defensible sources of scientific data, methods, and peer-reviewed Agency guidance on dose-response analysis. Expert read-across approaches are applied to evaluate data-poor chemicals where little to no data are available. All PPRTVs receive internal and external peer review and are publicly available.

Impact and Use: PPRTV assessments can be used in combination with exposure metrics to characterize the public health risks of a given chemical at a particular contaminated waste site. These risk characterizations can form the basis for risk-based decision-making, regulatory activities, and other risk management decisions designed to characterize and protect human health.

DEVELOPMENT OF PROVISIONAL PEER-REVIEWED TOXICITY VALUE (PPRTV) ASSESSMENTS

CONTACT: TERESA SHANNON (NCEA)

FY17 Products and Outputs – Highlights:

- * Delivered 12 PPRTV assessments → a total of 25 provisional toxicity values.
- * Seven of these PPRTV assessments applied NCEA-developed expert read-across approach on data-poor chemicals.
- * In collaboration with OLEM, implemented a new standard operating procedure for selecting and prioritizing chemicals for PPRTV development.
- * Due to high interest in evaluating the potential human health effects of *p*-chlorobenzene sulfonic acid, CalEPA and NCEA, in collaboration with EPA Region 9 (Pacific Southwest), worked together in aggregating extant toxicity study data leading to the development of a PPRTV assessment.
 - * Featured in ORD and Environmental Council of the States “*Partners for Meeting State Research Needs*” document.

**QUARTERLY REPORTS TO SUPERFUND TECHNICAL SUPPORT CENTER (STSC)
AND ECOLOGICAL RISK ASSESSMENT SUPPORT CENTER (ERASC)**

CONTACT: TERESA SHANNON (NCEA)

Description: Quarterly Reports consolidate information on Technical Support Center (TSC) activities that occurred within each region during the previous quarter, including support provided through the STSC and ERASC.

Purpose: The TSC respond to requests for technical assistance from EPA's program offices and regions at Superfund, Resource Conservation & Recovery Act (RCRA), and Brownfield sites



**QUARTERLY REPORTS TO SUPERFUND TECHNICAL SUPPORT CENTER (STSC)
AND ECOLOGICAL RISK ASSESSMENT SUPPORT CENTER (ERASC)**

CONTACT: TERESA SHANNON (NCEA)

The STSC provided support for OLEM and Regions 2, 3, 4, 7, and 9 through requests such as:

- * toxicity value searches,
- * review of a newly published paper investigating the mode of action of technical-grade toxaphene-induced mouse liver tumors,
- * comparison of the interpretations of the hazard database for cobalt and decisions made in the 2008 Cobalt PPRTV compared to a manuscript

The ERASC has on-going support for OLEM and Regions 2, 3, 4, 5, 7, and 10 through the development of response documents such as:

- * "Climate Change Issues In Ecological Risk Assessments at Hazardous Waste Sites"
- * "Separating Anthropogenic Metals Contamination from Background: A Critical Review of Geochemical Evaluations and Proposal of Alternative Methodology"
- * "Body-Weight Scaling of Acute and Chronic Toxicity: Comparison of Health and Wildlife Perspectives, and Proposal for Refinement of Wildlife Assessments"

APPORTIONING MULTIMEDIA EXPOSURE AND RISK ACROSS HUMAN AND ECOLOGICAL RECEPTORS

CONTACT: JEANETTE REYES (ORISE AT NCEA-RTP)

Purpose:

This research supports ORD by developing state-of-the-art methods for human health risk assessment that ~~will~~ may inform NCEA assessments and are simple and cost-effective for our partners at State and Local Agencies to apply.

Impact and Use:

The novel methodology developed through this project allows for quantification of risk associated with chemical exposures in which control of a single pollutant or of multiple co-pollutants impacts human health. This method will be directly useful for State and Local partners to minimize costs by focusing on the most impactful pollutant control strategies.

Description:

Several approaches may be used to inform the quantification of risk to chemical mixtures. A cumulative risk approach assesses the risk associated with exposure to multiple chemicals. This analysis evaluates two approaches, the Hazard Index/Hazard Quotient and Maximum Cumulative Ratio, to quantify the potential of concern over chemical co-exposures, using phthalate exposures as an example. This work falls under Project 6 (Cumulative Risk Assessment [CRA] Methods and Applications), Task 4 (Apportioning Multimedia Exposure and Risk across Receptors).

Deliverables:

2 related papers, 2 presentations and 1 award

Reyes, J. M.; Price, P. S. Temporal trends of cumulative risks from phthalates in biomonitoring data. *Environ. Sci. Technol.* **2018**, in preparation.

Reyes, J.; Price, P. An analysis of cumulative risks based on biomonitoring data for six phthalates using the Maximum Cumulative Ratio. *Environ. Int.* **2017**, under review.

Reyes, J. and Paul Price, **2017**. Trends in Cumulative Exposures of Six Phthalates in the United States from 2005 to 2014, International Society of Exposure Science, Oral Presentation. RTP, NC, USA. October 19.

Reyes, J. and Paul Price, **2017**. An Analysis of Cumulative Risks Indicated by Biomonitoring Data of Six Phthalates Using the Maximum Cumulative Ratio, Society of Toxicology, Poster Presentation. Baltimore, MD, USA. March 16. [**Top 5 Mixtures Specialty Section Abstracts Award**]

APPORTIONING MULTIMEDIA EXPOSURE AND RISK ACROSS HUMAN AND ECOLOGICAL RECEPTORS

CONTACT: JEANETTE REYES (ORISE AT NCEA-RTP)

HAZARD INDEX (HI) AND HAZARD QUOTIENTS (HQs) OVER TIME

Description

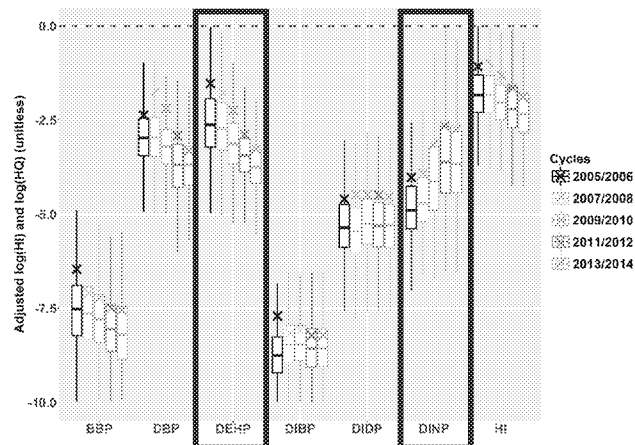
- Using six phthalates as a case study, population-wide temporal trends of HI are investigated for the past decade from the NHANES data set. HQ compares pollutant exposure to a reference value, and HI sums HQ across pollutants.

Results

- There was a sizable decrease in hazard from 2005-2014 in terms of percentage of participants with HIs of concern (5.1% to 0.8%) and mean hazard (0.34 to 0.15).
- Temporal trends show a decrease in DEHP hazards with increases in DINP hazards.

Impact

- Investigating population-wide hazards can be a means to prioritize co-exposures to chemicals of interest for epidemiological and toxicological studies of phthalate mixtures.
- Monitoring of phthalates continues to be important as mitigation strategies change, new phthalates enter the market, and population-wide hazards decrease.



APPORTIONING MULTIMEDIA EXPOSURE AND RISK ACROSS HUMAN AND ECOLOGICAL RECEPTORS

CONTACT: JEANETTE REYES (ORISE AT NCEA-RTP)

HAZARD INDEX (HI) AND MAXIMUM CUMULATIVE RATIO (MCR) OVER TIME

Description

- MCR measures the dominance of a single chemical within a mixture, defined as hazard divided by the maximum individual chemical-specific hazard.

Results

- Mean MCR consistently increases over time, indicating that mixtures are less dominated by individual chemicals.

Impact

- The MCR metric can be a means to prioritize by how much individual chemicals within a group affect hazard, especially among hazards of concern.
- An increasing MCR among phthalates demonstrates that as overall hazards decrease, remaining hazards of concern will only be properly identified through an investigation of mixtures.

